DEC 2 2 2004

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared:	November 8, 2004
Submitter:	Bayer HealthCare LLC
Address:	1884 Miles Avenue, P.O. Box 70 Elkhart, IN 46515 574.262.6928
Contact:	George M. Tancos Manager, Regulatory Affairs
Device:	Trade/Proprietary Name: Ascensia BRIO™ Blood Glucose Monitoring System Common/Usual Name: Blood Glucose Meter Document Control Number: K04 3158
Classification:	Division of Clinical Laboratory Devices Panel – Clinical Chemistry and Toxicology Classification Code – 75 CGA (Glucose Oxidase, Glucose)
Predicate Devices:	ASCENSIA ELITE™ Diabetes Care System
Device Description:	The Ascensia BRIO™ Blood Glucose Monitoring System consists of an electrochemical method-based meter and reagent sensor (test strips) designed for testing glucose by persons with diabetes or by healthcare professionals in the home or in healthcare facilities.
Intended Use:	The Ascensia BRIO™ Blood Glucose Monitoring System is for the Self-Monitoring of Blood Glucose as an adjunct to the care of person with diabetes.[1]

[1] "Consensus Statement on Self-Monitoring of Blood Glucose," Diabetes Care, Vol. 10, No. 1, January-February 1987, pp. 95.99

Technological Characteristics:	The Ascensia BRIO™ Blood Glucose Monitoring System test is based on the measurement of electrical current caused by the reaction of glucose with the reagents (glucose oxidase) on the electrode of the test strip. It is conceptually the same as other blood glucose monitoring products available for blood glucose testing. There are 50 test strips in a plastic bottle. The system is specific for glucose and has been referenced to plasma glucose values from fingerstick capillary samples. The System has a linear response to glucose from 30-550 mg/dL.
Assessment of Performance:	An evaluation of the Ascensia BRIO™ Blood Glucose Monitoring System was studied both internally and externally in a clinical setting by persons with diabetes. The studies demonstrated that users can obtain blood glucose results that are substantially equivalent to current methods for blood glucose.
Conclusion:	The results of clinical evaluations of the Ascensia BRIO™ Blood Glucose Monitoring System demonstrate that the device is equivalent in performance to the predicate devices and suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 22 2004

Mr. George M. Tancos
Manager, Regulatory Affairs
Bayer HealthCare LLC.
1884 Miles Avenue, P.O. Box 70
Elkhart, IN 46514-0070

Re: k043158
Trade/Device Name: Ascensia BRIO™ Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: November 12, 2004
Received: November 15, 2004

Dear Mr. Tancos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043158

Device Name: **Ascensia BRIO™ Blood Glucose Monitoring System**

Indications For Use:

The Ascensia BRIO™ Blood Glucose Meter is used with Ascensia® EASYFILL™ Blood Glucose Test Strips and ASCENSIA® EASYFILL™ CONTROL SOLUTIONS (Low, Normal, and High) for the measurement of glucose in whole blood. The Ascensia BRIO™ Blood Glucose Monitoring System is an Over-the-Counter (OTC) device used by persons with diabetes and by healthcare professionals in home settings and in healthcare facilities.

The Ascensia® Brio™ Blood Glucose Monitoring System is indicated for use with fingertip capillary whole blood specimens.

The frequent monitoring of blood glucose is an adjunct to the care of persons with diabetes.

Prescription Use _____ AND/OR Over-The-Counter Use **-XX-**
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K043158